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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,316	01/23/2004	Michael J. Borrelli	10546-109	8323

7590 06/13/2007  
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Chicago, IL 60610

EXAMINER
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CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,316	<b>Applicant(s)</b> BORRELLI, MICHAEL J.	
	<b>Examiner</b> Kimberly Chong	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 14-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8, 9, 11-13 and 32 is/are rejected.
- 7) ☐ Claim(s) 4, 7, 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 03/21/2007 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 11/22/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 03/21/2007, claims 1-32 are pending in the application. Claims 1-13 and 32 are currently under examination and claims 14-31 are withdrawn as being a non-elected invention.

### ***Response to Applicant's Arguments***

#### ***Claim Objections***

Claims 4, 7 and 10 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Re: Claim Rejections - 35 USC § 103***

The rejection of claims 1-3, 5-6, 8-9, 11-13 and 32 under 35 U.S.C. 103(a) as being unpatentable over Li et al. (of record), Frisan et al. (of record), Sert et al. (of

Art Unit: 1635

record) and Xu et al. (of record) is maintained for the reasons of record in the Office action mailed 11/22/2006.

Acknowledgment is made of applicant's arguments filed 03/21/2007, however they are not found persuasive. Applicant argues there is no motivation to combine the teachings of the above-cited references to arrive at the claimed invention.

Applicants argue Sert et al. teaches away from the use of CDT's for causing cell cycle arrest by DNA damage and teaches that CDT triggers cell cycle arrest by a method that is independent of DNA damage and does not induce double strand breaks. In response to applicant's arguments regarding Sert et al., the instant claims do not recite any functional language wherein the CDT causes double stranded breaks or DNA damage. The instant invention is drawn to a gene therapy vector comprising a polynucleotide encoding a gene for a CDT. Sert et al. teach CDT's cause cell cycle arrest and DNA damage and therefore one would have been motivated to incorporate a toxin gene, such as CDT for the purpose of treating cancer cells.

Applicants further argue Frisan et al. do not teach that cdtB, when used alone, is a good anti-tumor agent and argue that Frisan et al. teach that a combination of cdtB, cdtA and cdTC produce an active CDT. Applicant's argue that Frisan et al. do not teach or disclose any data that suggests CDT's are good anti-tumor agents because Frisan states "[t]he interference of CDT with the cell cycle make it a potentially good candidate for an anti-tumor agent". Applicant has taken this statement out of context. Frisan et al. states "[t]he interference of CDT with the cell cycle make it a potentially good candidate for an anti-tumor agent, *provided the toxin can be selectively delivered to the tumor*

Art Unit: 1635

cell.” [emphasis added]. This statement, when read in its entirety, clearly suggests to one of skill in the art that Frisan et al. teach CDT can be used as an effective anti-tumor agent. Further, claims 1-3, 6, 8-9 and 11-13 are broadly drawn to the use of any CDT gene and are not limited to the CdtB gene. Moreover, Frisan et al. teach on page 496, last paragraph, that “CdtB alone, when present intracellularly can induce cell cycle arrest.” Thus, Frisan et al. provides motivation to use a CDT gene as an anti-tumor agent and more specifically teach cdtB can be used alone to produce the same effects as cdtABC.

Applicants argue that Xu et al. do not teach using a vector including one or more suicide genes and the invention taught by Li et al. cannot be used alone as it does not induce DNA damage and must be used in combination with other therapies to treat cancer. In response to applicant’s arguments, the Xu et al. reference was not relied upon to teach using a vector including suicide genes, Xu et al. was relied upon to teach strategies for cancer therapy comprising administering toxins to cancer cells and one of skill in the art would have been motivated to use a CDT as an anti-tumor toxin. In response to applicant’s arguments that Li et al. cannot be used alone, Li et al. was not relied upon for teaching the claimed invention, otherwise it would have been used in a 102 rejection. Li et al. was relied upon, in combination with the above-cited references, to show that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Thus, the rejection of record is maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

Art Unit: 1635

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
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